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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,418	12/19/2001	Himanshu Patel	018489-002510US	2779

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/027,418

Applicant(s)

PATEL ET AL.

Examiner

Bradford C. Pantuck

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3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05-06-2005.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-13,24-39,41-48,61,62,69-72 and 74 is/are pending in the application.  
4a) Of the above claim(s) 24-31 and 61 is/are withdrawn from consideration.  
5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6,9-13,24-39,41-48,61,62,69-72 and 74 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

1. Claims 62, 69-72, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,638,233 B2 to Corvi et al.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

2. With regards to claims 62, 69-72, and 74, Corvi discloses in Figures 3 and 4 a method of debulking an artery, in accordance with the claimed invention. The catheter has a rotatable cutter (74) movable from an unexposed position to an exposed position and a collection chamber [the distal space inside of member (72)—adjacent to opening (76)]. The cutter rotates from a position inside the opening to a position in which it juts out of the opening [Fig. 4B]. Corvi discloses advancing the whole catheter distally (in direction (56)) [column 6, lines 1-6] to move the rotating cutter through occlusive material (as shown in Fig. 3B). The cutter and window maintain a

fixed position relative to each other, i.e. they do not move relative to each other while the cutting is taking place.

### *Conclusion*

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,475,226 B1 to Belef et al.

U.S. Patent No. 6,190,353 B1 to Makower et al.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6, 9-13, 24-39, 41-48, 61, 62, 69-72 and 74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-24 of copending Application No. 10/421979, claims 1-15 of copending Application No. 10/288581, claims 46-69 of copending Application No. 10/288559, and claims 1-11 of copending Application No. 10/288582. Although the

conflicting claims are not identical, they are not patentably distinct from each other because each of the respective application's specifications discloses deflecting the distal portion relative to the proximal portion to reveal the cutter through the cutting window.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Response to Arguments*

5. Applicant's arguments filed 05/06/2005, with respect to the rejection with prior art reference U.S. Patent No. 6,638,233 B2 to Corvi et al., have been fully considered but they are not persuasive. Regarding U.S. Patent No. 6,638,233 B2 to Corvi et al., Examiner maintains that Corvi discloses rotating the cutter while moving the whole catheter assembly forward: "*With the material capture needle 54 deployed, the catheter 50 would be pushed forward as indicated by arrow 56 to penetrated target material T*" [column 6, lines 3-6]. Further, Corvi teaches that the needle 54 is rotatable to go from an enclosed position to the deployed position of Fig. 4B.

When such a needle is driven (by the distal movement of the catheter) into tissue, the needle will inevitably pivot on its hinge, while contacting the body tissue.

Newton's third law states: "for every action there is an equal an opposite reaction."

The action of the tissue being driven into the distal face of the needle will *necessarily* cause the equal and opposite reaction of the needle rotating about its hinge (however slightly)—*unless the needle is to violate the generally accepted laws of physics.*

Examiner understands that the tip of the needle may cut through the tissue smoothly,

but maintains that when the tissue contacts the bottom/distal (diagonally facing) face of the needle this will push the needle back, causing it to rotate slightly about its hinge.

6. Regarding Applicant's contention that material cut by the needle 74 will end up beneath the needle rather than distal to the needle, Examiner disagrees. Although material will end up below the needle [see Fig. 4B], material will also accrue distal to the needle and proximal to parts of the needle. Without question, material will be located distal to the proximal parts of the needle.
7. Applicant's arguments, see "REMARKS", filed 05/06/2005, with respect to the rejection with prior art reference U.S. Patent No. 4,979,951 to Simpson have been fully considered and are persuasive. The rejection employing this reference has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C. Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BCP*  
BCP  
May 24, 2005

*12*  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
*5/26/05*